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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/558,472	04/25/2000	Michael R. Bristow	MYOG:004DIV1	8819

7590 07/09/2004

Steven L Highlander
Fulbright & Jaworski L L P
600 Congress Avenue
Suite 2400
Austin, TX 78701

EXAMINER	
SHUKLA, RAM R	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/558,472	BRISTOW ET AL.	
	Examiner	Art Unit	
	Ram R. Shukla	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *23*.

   Claim(s) withdrawn from consideration: *None*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☒ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). *5/24/04*.

10. ☐ Other: _____

RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit: 1632

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments have been fully considered, however they are not persuasive to obviate the pending rejections. The abstract by Robbins is not relevant to the instant case because the abstract is directed to a transgenic animal and the results/observation in a transgenic animal cannot be extrapolated to a method for introducing a gene in an subject by any route for effecting treatment of a disease. While the transgenic approach ensures presence of a transgene in every cell of an animal, no such inference could be expected when a transgene is administered to a subject by any route. Regarding applicants' arguments that the examiner ignored all the references except one and focussed on only one reference, it is noted that all the references were considered. It is emphasized that the refenrences listed were directed to a certain method and their method steps could not be extrapolated to any method/condition in general. In other words, these references did not provide evidence that the method of treating myocardial failure by administering a transgene by any route was routine at the time of the filing of the application (1997). None of the arts provided evidence that gene therapy for treating myocardial failure was routinely practiced and any route of administration in general could be used for practicing the claimed method that would have resulted in adequate expression of the claimed gene so as to effect treatment of myocardial failure. At best the the articles discussed that at the time of the invention, direct delvery to pericardium could be practiced at the time of the invention. It is emphasized that any post filing art could not be used in supporting enablement of the claimed invention since none of the post filing arts followed the method taught by the specification. In fact, the specification does not teach any specific method steps or specific guidance for practicing the claimed invention. In conclusion, the enablement rejection is maintained for reasons of record set forth in the previous office action of 3-19-04.

RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER